03/13/24 • BIG PHARMA › NEWS

Unfazed by 140+ Lawsuits, Merck to Test Single-Dose HPV Vaccine

Merck today announced two new initiatives for growing the global market for its human papillomavirus, or HPV, vaccines. The initiatives include the pharmaceutical giant's first single-dose HPV shots plus multivalent HPV vaccines designed specifically for Asian and African populations.

By Brenda Baletti, Ph.D.

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Pharmaceutical giant Merck today announced two new initiatives for growing the global market for its human papillomavirus (HPV) vaccines.

The company is developing a new investigational multivalent — meaning it targets many virus strains — HPV vaccine aimed at HPV types known to disproportionately affect African and Asian populations and people of African and Asian descent, the company said. Merck said it will begin testing the vaccine in humans in the fourth quarter of 2024.

The company also plans to launch two separate multiyear clinical trials to test the efficacy of a single dose of its Gardasil 9 HPV vaccine in females and males ages 16-26, in contrast to the company's three-dose regimen for the currently approved Gardasil shots. That trial also will start at the end of 2024.

Since 2019, Merck has invested more than $1.6 billion in manufacturing plants to increase the global supply of Gardasil. It nearly doubled its supply between 2017 and 2020 and again between 2020 and 2024 and plans to continue to grow

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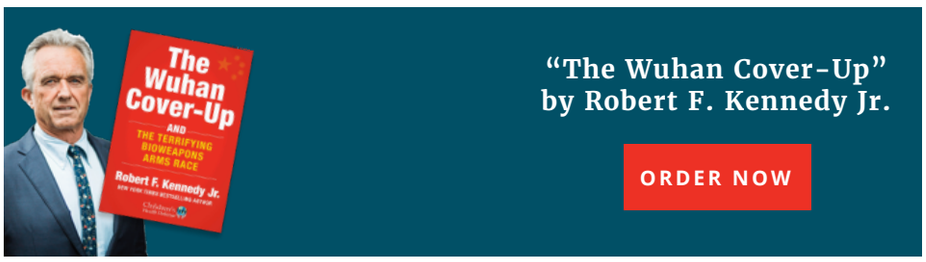
its supply capacity, it stated.

Merck's reported global 2023 profits from its Gardasil product line were $8.9 billion, up 29% from the previous year.

The company is currently facing 143 lawsuits in federal court from people who suffered a range of serious injuries after taking Gardasil, including autoimmune disorders, premature ovarian failure and cancer. There are also over 200 Gardasil injury claims pending in the Vaccine Court.



Racial and ethnic disparities in HPV infection

It has long been known that the distribution of HPV genotypes varies by race/ethnicity — a difference that persists when controlling for demographic and sexual behavior differences — and that the types of HPV targeted by the vaccine are not necessarily the predominant type among Black women.

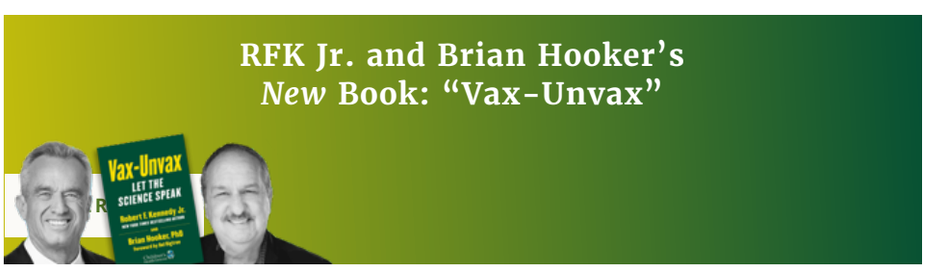
Yet, while proclaiming the HPV vaccine's effectiveness as a tool to fight cancer, until now Merck has not developed any vaccines to target the strains that affect African American women or women in Africa and Asia, where cervical cancer rates are highest.

"It's really kind of sad," Kim Mack Rosenberg, Children's Health Defense general counsel, told The Defender. "They ignored those women for a long time and now they are looking for a new way to market their products."

Rosenberg is co-author of "The HPV Vaccine On Trial: Seeking Justice For A Generation Betrayed."

In the U.S., the incidence of cervical cancer is 60% higher and mortality is more than two times higher for women of African descent relative to women of European descent. Yet African American women are two times less likely to be infected with "high-risk" HPV strains 16 and 18, targeted by all of the HPV vaccines.

Overall, research has found that non-Hispanic Black and Hispanic women have the lowest prevalence of HPV genotypes covered by currently available bi- and quadrivalent vaccines and the highest prevalence of genotypes not covered by any vaccine.



A single-dose recommendation?

The Centers for Disease Control and Prevention (CDC) recommends the HPV vaccine as part of routine vaccination, indicating a two-dose schedule for adolescents who begin vaccination before age 15 and a three-dose series for teens and young adults who begin the series between ages 15-26.

To boost global coverage, the World Health Organization (WHO) changed its dosing recommendations several times. When the vaccine first came on the market, the WHO recommended a three-dose course of any version of the

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vaccine — but in 2014, it changed its recommendation to two doses as part of routine vaccination.

Last year, the WHO announced that "a single-dose Human Papillomavirus (HPV) vaccine delivers solid protection against HPV," and it changed its recommendations again to "one or two dose schedules" for girls and women ages 9 and up, based on "evidence that has been emerging over past years." The WHO announcement did not cite any specific research behind the change.

Today's announcement suggests Merck had not yet conducted that research.

The WHO celebrated the single-dose recommendation as "less costly, less resource intensive and easier to administer," predicting that it would be a "game-changer," and adding "this single-dose recommendation has the potential to take us faster to our goal of having 90 percent of girls vaccinated by the age of 15 by 2030."

The Bill & Melinda Gates Foundation-backed Gavi, the Vaccine Alliance has been distributing the HPV vaccine in Africa since 2011. By the end of 2020, Gavi funded the launch of national HPV vaccination campaigns in 13 African countries.

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Vaccine injury lawsuits pile up in U.S.

The Gardasil vaccine has been linked to myriad adverse events worldwide. Some of the signature impacts observed following HPV vaccination include permanently disabling autoimmune and neurological conditions, such as postural orthostatic tachycardia syndrome, or POTS, fibromyalgia and myalgic encephalomyelitis/chronic fatigue syndrome.

A new study in the journal Vaccine found that adolescent girls who received the quadrivalent vaccine were more likely to develop several different types of autoimmune diseases than their unvaccinated counterparts in the year following vaccination.

The girls in the study were 4.4 times more likely to develop rheumatoid arthritis, 2.76 times more likely to develop juvenile idiopathic arthritis, 2.86 times more likely to develop thyrotoxicosis and 2.54 times more likely to develop idiopathic thrombocytopenic purpura.

This study adds to a large body of peer-reviewed scientific literature from the U.S., Australia, Denmark and Sweden, France, Japan, and Colombia and statistics published by public health agencies in each of these countries demonstrating plausible associations between HPV vaccination and autoimmune conditions.

Despite the widespread evidence of injuries associated with the vaccine, Merck continues to market it as "safe and effective."

However, the company faces nearly 200 complaints in the federal court system alleging that the HPV vaccine caused debilitating autoimmune complications.

The lawsuits allege the drugmaker fast-tracked Gardasil through the U.S. Food and Drug Administration's (FDA) approval process and deceptively conducted clinical trials to mask serious side effects and exaggerate the vaccine's effectiveness.

Many of the lawsuits were consolidated into multidistrict litigation. A single federal judge in North Carolina will hear 16 cases from the larger pool of lawsuits pending. They will serve as a series of "bellwether trials," the outcome of which will shape the process for the growing number of claims brought against Merck for Gardasil-related injuries.

The consolidation order allows Gardasil lawsuits filed throughout the country to move into coordinated discovery and pretrial proceedings.

Discovery is ongoing and the cases will likely be heard early next year.

Gardasil's long-growing market

Gardasil markets its products to adolescents and adults through age 45 to protect against HPV-related cancers, although Merck's clinical trials for Gardasil tested only whether the vaccine suppressed the targeted strains of HPV — not if the vaccine protected against cancer.

HPV is the most common sexually transmitted infection in the U.S. Most people will get the infection at some point in their lives, but 90% of infections clear on their own with no residual health consequences on clinical follow-up.

Cervical cancer is the cancer most commonly associated with certain types of high-risk HPV infections, which can cause cervical cell abnormalities.

However, HPV infection is not the sole risk factor for cervical cancer. It is thought to be one factor that works in combination with other exposures to several environmental or immunological inflammatory mechanisms.

Regular pap screening has been found to reduce by at least 80% the incidence of and mortality from cervical cancer among women.

Merck's Gardasil was first licensed in 2006 for use in girls and women ages 9-26 to prevent four high-risk strains of HPV.

The FDA in 2009 expanded the license for use in males ages 9-26 for the prevention of genital warts. In 2011, the CDC's Advisory Committee on Immunization Practices recommended it for routine use in boys.

In 2014, the FDA approved Gardasil 9, designed to protect against 9 HPV strains, for use in the prevention of HPV-related cervical, vaginal and vulvar cancers in females and HPV-related anogenital lesions and anal cancers in males and females.

The agency also expanded the recommended age range to ages 9-45 — for males and females.

In June 2020, the FDA added the prevention of oropharyngeal and other head and neck cancers to the list of indications for the HPV vaccine under the "accelerated approval licensure pathway."

Among U.S. adolescents ages 13-17, 76.0% received one or more doses of Gardasil in 2022 and 62.6% had received the entire vaccine series, which is still below the U.S. public health agencies' goal of vaccinating at least 80% of adolescents with Gardasil by 2030.

According to the WHO, 21% of girls globally had received one dose of the HPV vaccine in 2022, versus 16% in 2021 and 6% of males had received one dose.

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Brenda Baletti, Ph.D.

Brenda Baletti, Ph.D., is a senior reporter for The Defender. She wrote and taught about capitalism and politics for 10 years in the writing program at Duke University. She holds a Ph.D. in human geography from the University of North Carolina at Chapel Hill and a master's from the University of Texas at Austin.

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Best Newest Oldest

holisticpoet
a month ago

With eyes to see and ears to hear, we are fearfully and wonderfully made. There are those who wish to take that from us. They use deceit as false promises to lure us away from what we know to be true. Would our creator have us live where we cannot survive without what we create for ourselves? I tell you he has given us all we need to flourish, and that anything we create for ourselves takes us farther from the glory of our creator. Why else would they even want to force us to be subject to their toxins that they use to keep power over us?

6 0 Reply

tag → holisticpoet
a month ago

God wins. Unfortunately in todays world of brain dead zombies, that simple truth is disguised by politics, the AMA and all media. Rolling up the sleeve just more socially acceptable. So is dying in your 40's I guess. .

4 0 Reply

BarbaraCharis
a month ago

If all American parents understood how the human body worked, we would not be in this position. We all have mouths and they were designed for us to eat...nourishing food to create energy and good health. Would people knowingly put elements in their mouths, if they knew what they were; like graphene oxide, polysorbate80, aluminum, mercury, animal viruses, fluoride, formaldehyde, etc. and swallow them?
This is what they are permitting the PROFIT-SEEKING Medical Industry to inject directly into their bloodstreams. Do they really believe these substances will protect them and keep them well? Many of the above substances harm the mind & body!

4 0 Reply

Deanna → BarbaraCharis
a month ago

I Have heard many mothers say ....they feel they are protecting their daughters and sons from other reproductive and sexually transmitted disease...uh NOT. TELL the children not to have any sexual activity before marriage.

0 0 Reply

Ektor
a month ago

No matter how many people are murdered or harmed by these drugs, no pig pharma employee is ever hanged or sent to prison. These companies are more than able to pay the fines for their corruption. Even if they couldn't, the government would pay them because the medical industry is such a big chunk of the economy (20%).

2 0 Reply

Double_Up
a month ago

My daughters and wife never got the useless but dangerous HPV 'vaxx'. They will never fall for the lies.

2 0 Reply

Jennifo
a month ago

This was pushed on my minor daughter for years & I said hell no.

Now, it is being mandated in the military & therefore she may (as well as another son in the military) be forced to take these deadly shots.

I bathe them in prayer for God to protect them from any harm. That's all I can do. I beg them to stall & wait for as long as they can. But too often enough, they are bullied, pressured, threatened & punished in the military to take a ridiculous amount of BS deadly shots.

Has the military not learned it's lesson from convid??? This is angering & heart breaking for a parent.

1 0 Reply

Chrissy Smith
a month ago edited

Merck Pharmaceutical Company was established in 1891. In 1950 the president resigned to lead the first Biological Weapons Program in the US. They opened a plant in Maryland called Fort Detrick. From here plots his generational wealth at the hands of suffering… they conducted almost 300 known experiments within the course of 40-50 years, including with radioactive weapons test. The plant was shut down at the end of WWII and sold to Pfizer for commercial use… In the 1930s they injected black men in Alabama with syphilis! They literally caused the HIV/AID epidemic and now profit off it. Just like they do with cancer, polio, the flus, mumps, measles, Lyme disease, whooping cough, Ebola, West Nile, MERS, SARS, COV…TO WHAT END? When will America realize they are still the test subjects!

I'm in complete awe how any of this was even able to play out so quietly… the America people didn't have a chance! Especially after they killed JFK!

0 0 Reply

taytalove45
a month ago edited

cause the penalties are pennies to them!

0 0 Reply

tag
a month ago edited

Yes, lets all gather together to vax OUR CHILDREN MANY YEARS BEFORE THEY BECOME SEXUALLY ACTIVE. WTF COULD GO WRONG? As long as Gates gets the bucks nothing wrong here.

0 0 Reply

Gary Brown
a month ago

June 5, 2023 More U.S. Parents Reject HPV Vaccine Over Safety Concerns

A growing number of parents in the U.S. are choosing not to vaccinate their adolescent children for human papillomavirus (HPV), according to a new study published in the June 2023 edition of the journal Pediatrics.1 The study identified HPV vaccine uptake trends in an effort to develop strategies to combat increasing vaccine hesitancy.

https://thevaccinereaction....

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